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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,405	02/12/2004	Seogchan Kang	P06605US00	5865
27407 7590 05/17/2007 MCKEE, VOORHEES & SEASE, P.L.C. ATTN: PENNSYLVANIA STATE UNIVERSITY 801 GRAND AVENUE, SUITE 3200 DES MOINES, IA 50309-2721			EXAMINER VOGEL, NANCY S	
			ART UNIT 1636	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/777,405

Applicant(s)

KANG ET AL.

Examiner

Nancy T. Vogel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 4-66 is/are pending in the application.
- 4a) Of the above claim(s) 16-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-15, 66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Claims 1, 2, 4-66 are pending in the case.

Any rejection of record in the previous action not addressed in this office action is withdrawn. There are no new grounds of rejection that were not necessitated by applicants' amendment and therefore, this action is final.

Election/Restrictions

This application contains claims 16-65 drawn to an invention nonelected with traverse in the reply filed on 8/28/06. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4-15, 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Capecchi et al. (US 5,464,764) (cited by applicants in view of de Groot et al. (Nature Biotechnology Vol. 16 pp. 839-842, 1998), Grosjean-Courneyer et al. (US Patent 6,617,163).

Capecchi et al. disclose a method of identifying and selecting transformants comprising transforming a host cell with Agrobacterium comprising a vector containing a targeting construct comprising a first polynucleotide sequence encoding a negative selection marker linked to a fragment of DNA flanked by DNA sequences homologous to a polynucleotide to be targeted, wherein said DNA fragment is disrupted by a positive selection marker, and selecting transformants by subjecting a transformed host cell to a positive and a negative selection agent (see abstract, Fig. 1, col. 15 lines 42-58, col. 18, lines 41-61). The transformants resulting from knockout lack the negative selection marker, while ectopic, heterologous or illegitimate transformants express both a negative and a positive selection marker (see col. 5 lines 20-30). The negative selection marker confers susceptibility to an agent and may be the HSVtk gene or a bacterial endotoxin gene, while the positive selection maker may confer resistance to an antibiotic such as neomycin, hygromycin, bleomycin (see Table I). The Agrobacterium

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tumefaciens may be used (see col. 18 lines 41-61). The reference discloses that the vectors may be used to transform fungi (col. 15 lines 42-52).

The difference between the reference and the instant claims is that transformation of fungal cells, and in particular such filamentous fungi as *Aspergillus fumigatus*, *Botrytis cineria*, *Magnaporthe grisea* and *Fusarium oxysporum*, using *Agrobacterium* is not disclosed.

However, de Groot et al. disclose that any filamentous fungi may be transformed using *Agrobacterium tumefaciens* (see abstract, see Table 2, see page 841, second column). De Groot et al. use a wide variety of filamentous fungi, including *Aspergillus*, *Fusarium*, and *Neurospora* species (Table 2). The reference discloses that the *Agrobacterium tumefaciens* transformation technique may be used with any filamentous fungi in addition to plant cells and such yeast as *S. cerevisiae* (abstract, page 839 cols. 1-2). Grosjean-Courneyer et al. disclose transformation, including transformation using *Agrobacterium tumefaciens* of a wide variety of fungi including *Magnaporthe grisea*, *Aspergillus fumigatus*, *Botrytis cineria*, and all *Fusarium* species (see col. 6 line 45 – col. 7 line 9).

It would have been obvious to one of ordinary skill in the art to have used the positive/negative transformation method disclosed by Capecchi et al. and the *Agrobacterium* transformation method applied to fungi, including such well known strains as *Aspergillus fumigatus*, *Botrytis cineria*, *Magnaporthe grisea* and *Fusarium oxysporum* since de Groot et al. discloses that all filamentous fungi may be transformed using the *Agrobacterium tumefaciens* bacteria technique and since the art including

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Grosjean-Crouneyer et al. disclose that numerous filamentous fungi may be transformed with recombinant DNA techniques, and all of the above references are concerned with the transformation of fungi of interest using recombinant methods. One would have been motivated to do so by the desire to obtain the disclosed advantages of the positive/negative transformation technique of Capecchi et al., which include the ability to select against illegitimate (non-homologous) insertion of recombinant DNA into the genome of fungi of interest, and to obtain the well known advantages of the technique of *Agrobacterium tumefaciens* transformation which are disclosed in de Groot as being applicable to all fungi. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

This rejection is maintained essentially for the reasons made of record in the previous Office action, mailed 11/3/06, with claim 1 added due to applicant's amendment to the claim in which the limitation "fungus" was added to the claim.

Applicant's arguments filed 3/1/07 have been considered but have not been found convincing.

Applicants have argued that the Examiner has used impermissible hindsight to combine the references, and that there is no suggestion to combine must come from the prior art.

However, it is maintained that In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a

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reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the first reference teaches the general method of transformation and recombination, comprising using *Agrobacterium* comprising a vector containing a targeting construct comprising a first polynucleotide sequence encoding a negative selection marker linked to a fragment of DNA flanked by DNA sequences homologous to a polynucleotide to be targeted, wherein said DNA fragment is disrupted by a positive selection marker, and selecting transformants by subjecting a transformed host cell to a positive and a negative selection agent. The secondary references each teach that fungal cells can be transformed using *Agrobacterium tumefaciens*, and further specifically mention a wide variety of filamentous fungi, including *Aspergillus*, *Fusarium*, and *Neurospora* species in addition to plant cells and such yeast as *S. cerevisiae*, and Grosjean-

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Courneyer et al. disclose transformation using *Agrobacterium tumefaciens* of a wide variety of fungi including *Magnaporthe grisea*, *Aspergillus fumigatus*, *Botrytis cineria*, and all *Fusarium* species (see col. 6 line 45 – col. 7 line 9). Therefore, it is considered that one of skill in the art would have been motivated to use any technique involving *Agrobacterium* transformation, including using recombination and selection techniques known to be facilitated by such transformation, in a fungal host cell of interest, since the prior art taught both techniques for obtaining homologous recombination and selection using markers, via *Agrobacterium* transformation, and the use of *Agrobacterium* transformation in fungal cells.

The following is a new rejection necessitated by applicant's amendment:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite since they are dependent on cancelled claim 3. In the interest of compact prosecution, the claims are examined as if they are dependent on claim 1.

Conclusion

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NV
5/7/07


NANCY VOGEL
PRIMARY EXAMINER